

### REMARKS

Claims 1, 2, 8, 9, 21 and 26 have been amended. No new matter has been added.

Support for the amendments may be found throughout the specification, for example in p. 11, lines 10-13, p. 28, lines 14-17, p. 33, line 3 and in the originally filed claims. Claim 26 has been cancelled without prejudice. Applicants reserve the right to prosecute the subject matter of those claims in a continuing application at a later date. New claim 48 has been added. No new matter has been added. Support for the new claim may be found throughout the specification, for example, at p. 15, lines 8-10 and in the originally filed claim 9.

The specification has been amended to recite the date of deposit for *Lactobacillus sake* strain 570 and the complete name and full street address of the depository.

Applicants thank the Examiner for withdrawing the previous objection to the specification and the claims and the previous rejection of claims.

Claims 1-3, 7-9, 13-22, 24, 27-29, 32-34 and 44-48 are currently pending.

### CLAIM OBJECTION

The Examiner has objected to the term “an viable lactic acid microorganism” in claim 1 as being grammatically incorrect. See Office Action at p. 5. Claim 1 has been amended to recite “an isolated viable lactic acid micro-organism” and as such amended claim 1 is grammatically correct. Applicants respectfully request the withdrawal of this objection.

The Examiner has objected to claim 2 “as being of improper dependent form for failing to further limit the subject matter of the previous claim.” Id. Applicants have amended claim 2 to be an independent claim. Applicants respectfully request the withdrawal of this objection.

The Examiner has objected to claim 8 “as being of improper dependent form for failing to further limit the subject matter of the previous claim.” Id. Specifically, the Examiner states that “[c]laim 8 does not further limit claim 1 because by definition an EPS is a polysaccharide.” Id. Claim 8 has been amended to delete reference to the term “polysaccharide.” Applicants respectfully request the withdrawal of this objection.

The Examiner has stated that “should claim 24 be found allowable, claim 26 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof.” Id. In an effort to

expedite prosecution and not in acquiescence to the rejection, Applicants have cancelled claim 26 without prejudice. Applicants respectfully request the withdrawal of this objection.

### **CLAIM REJECTION**

#### ***Rejection of claims under 35 U.S.C. § 101***

The Examiner has rejected claims 1, 3, 7-9, 15-17 and 19-20 under 35 U.S.C. § 101 as being “directed to non-statutory subject matter” and reading “on a product of nature.” See Office Action at p. 3. Claims 3, 7-9, 15-17 and 19-20 depend from independent claim 1.

Applicants thank the Examiner for the suggested amendment. See Office Action at p. 4. Applicants have amended claim 1 to refer to “an isolated viable lactic acid micro-organism.” Accordingly, claim 1 does not refer to a product of nature. Applicants respectfully request the withdrawal of this rejection with respect to claim 1 and dependent claims thereof.

#### ***Rejection of claims under 35 U.S.C. § 112, first paragraph***

##### ***Written Description***

The Examiner has rejected claims 1-3, 7-9, 13-22, 24, 26-29, 32-34 and 44-47 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. See Office Action at p. 6.

The Examiner states that “[t]he claims are drawn to a vast genus of enzymes synthesized by said microorganism and an exopolysaccharide (EPS) produced by said enzyme.” Id. The Examiner contends that “the specification is equally silent with regard to which EPS is capable of being modulated (see claim 15) and which EPS has the ability to improve the texture, body, mouth feel, viscosity, structure and/or organoleptic properties of a food containing said EPS as an ingredient (see claim 17).” Id. The Examiner further contends that “the specification is silent with regard to which EPS has the capacity to reduce the production of gas by the gastrointestinal microorganism when used as ingredients [in] products for consumption.” See Office Action at p. 6-7.

Applicants respectfully traverse this rejection. Applicants wish to point out that the Examples describe the culture of the *Lactobacillus sakei* strain 570. See Examples 6-8 and Figures 8, 11, 12, 13 and 16 of the specification. In addition, the culture medium described on

page 42, lines 3-5, is a milk-based medium which is suitable for consumption. It is clear from the Examples that by culturing *Lactobacillus sakei* strain 570 in this medium, exopolysaccharides are produced (see, for instance, Figures 8, 11, 12, 13 and 16) and that the amount of EPS varies depending on the nature of the culture medium (such as the amount of maltose in the culture medium) and the culture conditions (such as the length of culture time and pH of the culture medium).

Moreover, it is clear from the actual presence of Examples 6-8 in the specification that the skilled person had possession of the claimed invention when the application was filed. In addition, Applicants wish to point out that the culture of lactic acid bacteria in edible culture mediums, such as milk, to generate edible products for consumption (such as yoghurt) was well known in the art. It was also well known in the art that such products contain viable lactic acid bacteria if they were not, for example, pasteurized after the culture was carried out, Examples of such products include pro-biotic yoghurt drinks and live (bioactive) yoghurts. Hence, the skilled person, once taught the lactic acid bacterial strain *Lactobacillus sakei* strain 570, would have readily been able to culture said microorganism in an edible medium (such as milk) to produce an edible product for consumption (such as yoghurt) using techniques which are routine in the art.

Moreover, the skilled person would have readily considered that in order for the microorganism to be viable in a culture it would produce enzymes. The skilled person does not need to know the types of enzymes which the microorganism produces in order to work the invention. The skilled person would simply realize that if he cultures *Lactobacillus sakei* strain 570, it results in the production of EPS.

In addition, the skilled person would have readily been able to verify that *Lactobacillus sakei* strain 570 was actually producing EPS by determining, for example, the viscosity of the culture medium using techniques which are routine in the art (such as by using the DVII Viscometer as described on page 43, lines 24-26, of the present application). Again, the skilled person does not need to be taught the types of EPS which the microorganism produces. The skilled person simply needs to know that if he cultures *Lactobacillus sakei* strain 570 it results in the production of EPS.

To summarize, the skilled person once taught the isolated *Lactobacillus sakei* strain 570 according to the present application would have readily cultured the lactic acid bacterium, in culture media suitable for consumption, using techniques which are routine in the art. Accordingly, the specification sufficiently describes the claimed invention in full, clear, concise and exact terms and satisfies the written description requirement of 35 U.S.C. § 112, first paragraph. Thus Applicants respectfully request reconsideration and withdrawal of this rejection.

***Enablement***

The Examiner has rejected claims 1-3, 7-9, 13-22, 24, 26-29, 32-34 and 44-47 under 35 U.S.C. § 112, first paragraph, "as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." See Office Action at p. 9.

Specifically, the Examiner states that "[b]ecause it is not clear that cell lines possessing the properties of *Lactobacillus sakei* strain 570 are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the claims require the use of a suitable deposit for patent purposes a deposit in a public repository is required." *Id.*

Applicants respectfully submit a declaration from Andrew John Morgan, Chief Scientific Officer at Danisco (attached at Appendix A, "Declaration") stating that the deposit of *Lactobacillus sakei* strain 570 was made to the International Depository Authority (DSMZ- Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH ("DSMZ")) as DSM 15889 on September 2, 2003, under the terms of the Budapest Treaty. The Declaration states that the deposits have been made under conditions of assurance of (a) that all restrictions imposed by the depositor on the availability to the public of the deposited microbial strains will be irrevocably removed upon the granting of the patent and (b) access to the deposit will be available during pendency of the patent application making references to the deposit to one determined by the Commissioner of Patents and Trademarks to be entitled thereto under applicable statutes and regulations.

Applicants attach a statement of corroboration that *Lactobacillus sakei* strain 570 described in the specification as filed is the same as that deposited in the depository. This

statement of corroboration was filed in the USPTO on February 20, 2008. Copies of the transmittal letter, statement of corroboration and receipt of deposit are attached at Appendix B. Applicants have additionally amended the specification to recite the date of the deposit and the complete name and full street address of the depository.

Accordingly, Applicants believe that Applicants have informed and demonstrated to a person having ordinary skill in the art how to use the invention commensurate in scope with the claims. Applicants respectfully request reconsideration and withdrawal of this rejection with respect to claims 1-3, 7-9, 13-22, 24, 26-29, 32-34 and 44-47.

***Rejection of claims under 35 U.S.C. § 112, second paragraph***

The Examiner has rejected claims 1-3, 7-9, 13-22, 24, 26-29, 32-34 and 44-47 under 35 U.S.C. § 112, second paragraph as being indefinite. See Office Action at p. 13.

Specifically, the Examiner contends that “[c]laim 1 is rendered vague and indefinite by the use of the phrase ‘comprising an viable lactic microorganism, an enzyme synthesized by said microorganism and an exopolysaccharide produc[t] of said enzyme.’” Id. Applicants wish to point out that the skilled person on reading the application as a whole would have readily understood that before the microorganism is cultured, the culture medium will not include (i) the enzymes produced (i.e. synthesized) by the microorganism and (ii) the EPS produced by the enzyme acting on a substrate in the culture medium. However, the skilled person would have readily understood that, once the microorganism has been cultured, the medium, and thus the composition, will include both the enzyme and the EPS. Accordingly, claim 1 and dependent claims thereof are not indefinite and the claims as a whole would apprise one of ordinary skill in the art of its scope. Applicants respectfully request reconsideration and the withdrawal of this rejection.

The Examiner further contends that “[c]laim 21 is rendered vague and indefinite by the use of the terms ‘concentrated form.’” Id. Not in acquiescence to the rejection but in an effort to expedite prosecution, claim 21 has been amended to the effect that the composition includes a high concentration of the viable micro-organism and/or the enzyme synthesized by the micro-organism and/or the EPS produced by the enzyme. Accordingly, claim 21 as a whole would

apprise one of ordinary skill in the art of its scope. Applicants respectfully request reconsideration and the withdrawal of this rejection.

The Examiner additionally contends that “[c]laim 24 is rendered vague and indefinite by the use of the term ‘component.’” Id. Applicants respectfully direct the Examiner to the specification on p. 24, line 20 to p. 27, line 30 where examples of suitable components are clearly detailed and include, amongst others, flavoring agents and coloring agents. Thus, the skilled person, on reading the application as a whole, would have readily understood that the term “component” referred to any component — such as strawberry flavoring - which could be mixed with ‘a composition for consumption according to claim 1’ thus resulting in a product for consumption being produced e.g. strawberry flavored yoghurt. In other words, the skilled person would not have used a component which cannot be used in foodstuffs (such as a coloring agent which is not allowed by the US food regulatory authorities). Accordingly, claim 24 as a whole would apprise one of ordinary skill in the art of its scope. Applicants respectfully request reconsideration and the withdrawal of this rejection.

The Examiner alleges that “[c]laim 29 is rendered vague and indefinite by the use of the terms ‘functional food.’” Id. The term “functional food” is clearly defined on page 33, line 1-27 (especially lines 5-7) of the specification. It is clear from this definition that a functional food imparts more to the consumer than a nutritional effect. One example of a beneficial effect is improving the bacterial flora and fauna of the intestine. Accordingly, claim 29 as a whole would apprise one of ordinary skill in the art of its scope. Applicants respectfully request reconsideration and the withdrawal of this rejection.

#### **Patentability of new claims 48-50**

New claim 48 depends from independent claims 1 or 2. New claims 49 and 50 are independent claims. As previously discussed, none of the above-mentioned references teach or suggest a composition as described in claims 1, 2, 49 and 50. As such, new claims are patentable for at least the reasons described above.

**CONCLUSION**

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the pending rejections. Applicants believe that the claims now pending are in condition for allowance. The Commissioner is authorized to charge \$ 220 to the Deposit Account 19-4293 for the additional independent claim fee. The Commissioner is authorized to charge \$ 52 to the Deposit Account 19-4293 for the claim fee.

Should any fees be required by the present Amendment, the Commissioner is hereby authorized to charge Deposit Account **19-4293**.

Respectfully submitted,

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